



4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2018-N-2605]

Center for Devices and Radiological Health: Experiential Learning Program

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration's (FDA) Center for Devices and Radiological Health (CDRH or Center) is announcing the 2019 Experiential Learning Program (ELP). This training is intended to provide CDRH and other FDA staff with an opportunity to understand laboratory practices, quality system management, patient perspective/input, and challenges that impact the medical device development life cycle. The purpose of this document is to invite medical device industry, academia, and health care facilities, and others to participate in this formal training program for CDRH and other FDA staff, or to contact CDRH for more information regarding the ELP.

DATES: Submit electronic proposals for participation in the ELP at [ELP@fda.hhs.gov](mailto:ELP@fda.hhs.gov) within the dates provided at the ELP website at

<https://www.fda.gov/scienceresearch/sciencecareeropportunities/ucm380676.htm>.

ADDRESSES: You may submit comments as follows:

*Electronic Submissions*

Submit electronic comments in the following way:

- Federal eRulemaking Portal: <https://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including

attachments, to <https://www.regulations.gov> will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on <https://www.regulations.gov>.

- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions" or submit electronic proposals to [ELP@fda.hhs.gov](mailto:ELP@fda.hhs.gov)).

#### *Written/Paper Submissions*

Submit written/paper submissions as follows:

- Mail/Hand delivery/Courier (for written/paper submissions): Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in "Instructions."

*Instructions:* All comments received must include the Docket No. FDA-2018-N-2605 for "Center for Devices and Radiological Health: Experiential Learning Program." Received

comments will be placed in the docket and are publicly viewable at <https://www.regulations.gov> or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday.

- **Confidential Submissions**--To submit a comment with confidential information that you do not wish to be made publicly available, submit your requests only as a written/paper submission, or submit electronically to [ELP@fda.hhs.gov](mailto:ELP@fda.hhs.gov). You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states "THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION." The Agency will review this copy, including the claimed confidential information, in its consideration of requests. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on <https://www.regulations.gov>. Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your requests and you must identify this information as "confidential." Any information marked as "confidential" will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of requests to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: <https://www.gpo.gov/fdsys/pkg/FR-2015-09-18/pdf/2015-23389.pdf>.

*Docket:* For access to the docket to read background documents or the electronic and written/paper comments received, go to <https://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, into the "Search" box and follow the

prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Christian Hussong, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, Rm. 3283, Silver Spring, MD 20993-0002, 240-402-2246, or ELP Management, ELP@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

CDRH is responsible for ensuring the safety and effectiveness of medical devices marketed in the United States. Additionally, CDRH assures patients and providers have timely and continued access to high-quality, safe and effective medical devices. Continuing our 2016 and 2017 priorities of Partnering with Patients and Promoting a Culture of Quality and Organizational Excellence, adding our 2018-2020 Strategic Priorities of Simplicity, Collaborative Communities and Employee Engagement, Opportunity, and Success, overlaid by our constant strive for patient safety and innovation highlights our need to understand the perspective of our stakeholders. The Center encourages applicants to consider including opportunities to discuss innovation, patient perspective, patient safety, incorporating quality system design and management, simplification principles, and utilization of collaborative communities in their proposal(s) as they contribute to the success of the device development life cycle.

CDRH is committed to advancing regulatory science, providing industry with predictable, consistent, transparent, and efficient regulatory pathways, and helping to ensure consumer confidence in medical devices marketed in the United States and throughout the world. The ELP is intended to provide CDRH and other FDA staff with an opportunity to understand

the laboratory and manufacturing practices, quality system management, patient perspective/input, simplification principles, and other challenges and how they impact the medical device development life cycle. ELP is a collaborative effort to enhance communication with our stakeholders to facilitate medical device reviews. The Center is committed to understanding current industry practices, innovative technologies, regulatory impacts and needs, and how patient perspective/input, safety and quality systems management advance the development and evaluation of medical devices, and monitoring the performance of marketed devices.

These formal training visits are not intended for FDA to inspect, assess, judge, or perform a regulatory function (e.g., compliance inspection), but rather, they are an opportunity to provide CDRH and other FDA staff a better understanding of the products they review, and how they are developed. Additionally, it is to understand challenges related to quality systems development and management and simplification in processes, patient preferences and safety, in the product life cycle, and how medical devices fit into the larger health care system. CDRH is formally requesting participation from industry, academia, and clinical facilities, medical device incubators and accelerators, health technology assessment groups, and those that have previously participated in the ELP or other FDA site visit programs.

Additional information regarding the CDRH ELP, including current areas of interest, submission dates, a sample site visit request, and an example of a site visit agenda, is available on CDRH's website at:

<https://www.fda.gov/scienceresearch/sciencecareeropportunities/ucm380676.htm>.

## II. CDRH ELP

### *A. Areas of Interest*

In the ELP training program, groups of CDRH and other FDA staff will observe operations in the areas of research, device development, Digital Health, incorporating patient information and reimbursement, manufacturing, quality management principles, and health care facilities. The areas of interest for visits include various topics identified by managers at CDRH and other areas within FDA. These areas of interest are listed on the ELP website and are intended to be updated quarterly.

To submit a proposal addressing one of the Center's areas of interest, visit the link for the table of areas of interest at:

<https://www.fda.gov/ScienceResearch/ScienceCareerOpportunities/UCM380676.htm>.

Once you have determined an area of interest to address in your ELP proposal, follow the instructions in section III to complete the site visit request template and agenda provided at:

<https://www.fda.gov/downloads/ScienceResearch/ScienceCareerOpportunities/UCM392988.pdf>  
and at:

<https://www.fda.gov/downloads/ScienceResearch/ScienceCareerOpportunities/UCM487190.pdf>.

Submit all proposals at [ELP@fda.hhs.gov](mailto:ELP@fda.hhs.gov) within the dates provided at the ELP website at: <https://www.fda.gov/scienceresearch/sciencecareeropportunities/ucm380676.htm>.

### *B. Site Selection*

CDRH and FDA will be responsible for its own staff travel expenses associated with the site visits. CDRH and FDA will not provide funds to support the training provided by the site to the ELP. Selection of potential facilities will be based on CDRH and FDA's priorities for staff training and resources available to fund this program. In addition to logistical and other resource

factors, all sites must have a successful compliance record with FDA or another Agency with which FDA has a memorandum of understanding (if applicable). If a site visit involves a visit to a separate physical location of another firm under contract with the site, that firm must agree to participate in the ELP and must also have a satisfactory compliance history, and must be listed in the proposal along with a Facility Establishment Identifier number, if applicable.

### III. Request to Participate

Information regarding the CDRH ELP, including a sample request and an example of a site visit agenda, and submission dates is available on CDRH's website at:

<https://www.fda.gov/scienceresearch/sciencecareeropportunities/ucm380676.htm>. Proposals to participate should be submitted at [ELP@fda.hhs.gov](mailto:ELP@fda.hhs.gov), within the dates provided at the ELP website at: <https://www.fda.gov/scienceresearch/sciencecareeropportunities/ucm380676.htm>.

Dated: July 24, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018-16177 Filed: 7/27/2018 8:45 am; Publication Date: 7/30/2018]